

Research and Special Programs Administration 400 Seventh St., S.W. Washington, D.C. 20590

Ref. No. 01-0168

AUG 1 3 2001

Mr. William G. Warder Air Freight Center, Inc. Kansas City International Airport P.O. Box 20104 Kansas City, MO 64195

Dear Mr. Warder:

This responds to your letter of June 26, 2001, regarding the classification of drugs or medicines as Consumer Commodity, ORM-D under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Your questions have been paraphrased and answered as follows:

- Q1. May a drug or medicine used solely for animals be described as "Consumer Commodity, ORM-D?"
- A1. The answer is yes. The definition of "Consumer commodity" in § 171.8 states that the term includes drugs and medicines. This applies even if the drug or medicine is used solely on animals, provided it is listed in the U.S. Pharmacopeia.
- Q2. May raw materials (chemicals intended to become a drug or medicine) that are listed in the U.S. Pharmacopeia be described as "Consumer Commodity, ORM-D?"
- A2. The answer is no. The material must be in a form intended or suitable for sale and household use. In this scenario only materials that are in a final form as a drug or medicine qualify for shipment as Consumer Commodity, ORM-D.

I hope this information is helpful.

Sincerely

John A. Gale

Transportation Regulations Specialist Office of Hazardous Materials Standards



KANSAS CITY INTERNATIONAL AIRPORT

P.O. BOX 20104

KANSAS CITY, MO 64195

Mr. Edward T. Mazzullo, Director Office of Hazardous Materials Standards Research and Special Programs Administration US Department of Transportation 400 Seventh Street, S.W. Washington, D.C. 20590

Monday, June 26, 2001

Dear Mr. Mazzullo,

Subject: Request expansion of, DOT Letters of Interpretation \ 10/02/2000 171.8; Consumer Commodities, reclassification of drugs or medicines; animal.

I have a client that manufacturers ANIMAL drugs rather than human drugs. Of course, the same FDA approval is necessary before these products can be marketed. They are also listed in the U.S.P.

- First, does the "Consumer Commodity" term for drugs and medicines found in 171.8 apply to animal drugs and medicines?
- Second, Are the raw materials, also listed in the U.S.P. as "drugs and medicines" subject to any restrictions beyond the requirements for "Consumer Commodities"?
- Or for my benefit, can any chemical intended to become a "drug or medicine" listed in the U.S.P., and which qualifies for reclassification as a "consumer commodity" be reclassified?

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Consumer Commodity 01-0168

William G. Warder, Agent

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